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Thomas L. Mount, M.D.
Mark R. Fox, M.D.

CARDIOLOGY

Jerome F. Beekman, M.D., F.A.C.C.

ENDOCRINOLOGY

Leroy L. Schroeder, M.D.

GASTROENTEROLOGY

Robert L. Heacock, M.D.
Randal E. Huff, M.D., Ph.D.

HEMATOLOGY, ONCOLOGY

Ronald A. Pohlmeyer, M.D.
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Rick D. Watson, M.D.

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OFFICE MANAGER

Terry W. Yunker

1621 '99 MAR 24 P2:11

February 4, 1999

Igor Cerny, Pharm. D.
Federal Drug Administration, HFD 21
5630 Fishers Lane
Rockville, Maryland 20857
Attn: Advisor and Consulting Staff

Re: Colloidal Silver

Dear Dr. Cerny:

I have recently been informed that a number of special interest groups are looking for the FDA to approve products not on the USP or NF list for pharmacy compounding. One of these items is colloidal silver.

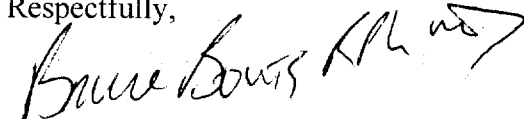
I have had the opportunity to have seen three cases of argyria over the past 20 years. Two of these cases were in the past six years of my practice in medicine. Over this time, I have had the opportunity to review the literature on silver on several occasions.

I know of no information in the past 25 years that would credibly suggest silver to be a useful alternative for any treatment. I am frightened by the possibility of pharmacists or other individuals using this to treat benign conditions orally. Though argyria is a relatively benign condition, the disfigurement caused by this is substantial and preventable, but sadly untreatable. I would think this would be a very substantial liability risk for a pharmacist, since this is a well recognized complication of a compound that should be relegated to a history of pharmacy text.

As a licensed pharmacist and board certified internist with extensive exposure to infectious disease and use of antibiotics, I cannot think of a single, good reason that a pharmacist should be compounding this agent. I am very embarrassed that a pharmacist might consider this product, given the wealth of alternative agents.

Please do not hesitate to call or write should you have any further questions or concerns, or if I can be of any assistance.

Respectfully,



Bruce A. Bouts, M.D.

BAB/jw

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1622 '99 MAR 24 P2:11

February 4, 1999

ATTN: Advisor & Consultant Staff
Igor Cerny, Ph.D.
FDA HFD 21
5630 Fishers Lane
Rockville MD 20857

Re: Hydrazine Sulfate

Dear Dr. Cerny:

Approximately 18 months ago, I was deluged with drug questions regarding a "dietary supplement", Hydrazine Sulfate. You may recall this relative of rocket fuel which was made popular by *Penthouse Magazine* claiming to have cured Bob Guccione's wife of breast cancer.

I had the opportunity to review the bulk of the world's literature on Hydrazine provided to me by the Drug Information Center at Ohio Northern University. In the studies shown at that time, I could see no reasonable use for Hydrazine and spent quite a bit of time discussing this issue with a remarkable number of patients who walked through my door demanding access to this product.

Shortly upon Mrs. Guccione's death, the fad passed. To date, there has been no reasonable indication for this inexpensive product.

While Hydrazine may indeed be useful as a rocket fuel, its sulfate salt does not appear to be of any use in the treatment of human malignancies or increasing the appetite in people suffering from malignancies. I really do not see a reason for this to be included in a compounding protocol.

Please do not hesitate to call or write should you have any further questions or concerns.

Respectfully,



Bruce A. Bouts, M.D.

BAB/ch